FIRST COAST SERVICE OPTIONS
MAC - PART A/B
LOCAL COVERAGE DETERMINATION

LCD Database ID Number
L36775

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09101 - Florida
09201 – PR/USVI
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type
MAC – Part A/ B

LCD Title
Prostatic Urethral Lift (PUL)

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CMS National Coverage Policy

Language quoted from CMS National Coverage Determination (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

Title XVIII of the Social Security Act (SSA)
Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Primary Geographic Jurisdiction
Florida
Puerto Rico/Virgin Islands

Oversight Region
Region IV

Original Determination Effective Date
10/31/2016

Original Determination Ending Date
N/A

Revision Effective Date
N/A

Revision Ending Date
N/A

Indications and Limitations of Coverage and/or Medical Necessity

Benign prostatic hyperplasia (BPH) is a common age-related noncancerous condition in men that is characterized by enlargement of the prostate gland which may cause symptoms of urinary outlet obstruction. Symptoms typically include increased urinary frequency, urgency, incontinence, straining; nocturia; decreased and intermittent force of the stream; hematuria; and the sensation of incomplete bladder emptying. Since BPH is a progressive enlargement, treatment usually starts with conservative management (e.g. avoid diuretics at night to reduce nocturia) and progresses to medical management with pharmacotherapy (e.g., alpha-blockers, 5-alpha-reductase inhibitors) and if medication management is not sufficient, surgical intervention. There are many different surgical approaches including transurethral needle ablation [TUNA], transurethral microwave thermotherapy [TUMT]), and transurethral prostatectomy [TURP]. The choice of treatment for urinary outlet obstruction due to BPH should be based on the individual's presentation and anatomy, the surgeon's training and experience, and a discussion of the potential benefit and risks for complications.

Prostatic Urethral Lift (PUL)

UroLift® was approved by the FDA on September 13, 2013 as a permanent implant to relieve low or blocked urine flow in men aged 50 and older with BPH. The UroLift system is a minimally invasive implant developed to treat lower urinary tract symptoms (LUTS) related to urinary outflow obstruction secondary to BPH in men 50 years of age or older. In this procedure, permanent implants (made from common implantable materials: nitinol, stainless steel, and polyethylene terephthalate) are delivered trans-prostatically to retract the enlarged lateral lobes of the prostate. This procedure dilates the prostatic urethra in individuals leading to improvement in LUTS symptoms without the need for surgical resection or the application of thermal energy to the prostate.

It also important to recognize that, as published in the Federal Register, Vol. 78, No. 152, Wednesday, August 7, 2013, page 48165, “FDA approval or clearance alone does not entitle that technology to Medicare coverage.” The criteria used to obtain FDA approval are different from those used to determine if the device is reasonable and necessary for the Medicare population. In determining
whether the UroLift system meets Medicare criteria for coverage as found in the IOM 100-08, Chapter 13 §13.5.1, the available published literature was reviewed and briefly summarized below.

Several authors have published non-comparative case series: Chin et al. (2012), McNicholas, et al. (2013), and others. These studies have shown that the procedure is well tolerated with minimal side effects, low rates of erectile dysfunction, and reduced symptoms of obstruction.

In addition to the case series, there are now several prospective comparative trials with data out to 3 years. Roehrborn et al. (2013) reported the first randomized trial of a PUL device for treatment of LUTS secondary to BPH in men aged > 50 years with an American Urological Association Symptom Index (AUASI) of > 13, a maximum flow rate of 12 ml/second or less, and a prostate of 30 to 80 cc were randomized 2:1 to PUL or sham. The sham consisted of rigid cystoscopy with sounds mimicking those heard with the PUL placement. Roehrborn et al. (2015), have subsequently published 3 year follow data for this cohort. While there are methodological concerns related to individuals lost to follow-up, the initial improvements in obstruction symptoms noted in the 1 year study were confirmed and, from a QOL perspective, there was no new ejaculatory or erectile dysfunction and adverse events were described as mild and transient. There was a 5% retreatment rate at one year. McVary et al. (2013) analyzed the sexual function of the men in this same study immediately and found no evidence of degradation in erectile or ejaculatory function after PUL. In addition, Cantwell et al. (2014) conducted a prospective, randomized, controlled, and “blinded” crossover trial of PUL in patients with LUTS due to BPH in 19 centers in the USA, Canada, and Australia. Men > 50 years old with an IPPS > 13, a Qmax of < 12 ml/s, and a prostate of 30-80 mL were enrolled. Control patients underwent a sham procedure similar to the case series and the Roehrborn trial, there were improvements in subjective and objective parameters of urinary obstruction, sexual function was maintained, and adverse events were primarily mild. In addition to the methodological concerns, the available data are still of relatively short duration (3 years). BPH is a progressive condition and men with BPH often live many decades. Thus, 3 year follow-up is not sufficient to detect long-term problems associated with this technique. Potential long-term problems might include prostate infections, implant migration, or interference with subsequent prostate procedures (be they for BPH, prostate cancer, or other conditions).

In addition to peer-reviewed literature, evidence based clinical guidelines were also reviewed. While the American Urological Association has a guideline on BPH, it has not been updated recently and provides no recommendation regarding PUL.

Guidance from the National Institute for Health and Clinical Excellence (NICE, 2014) states: "Current evidence on the efficacy and safety of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to BPH is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit."

Medicare coverage is available when certain criteria are met. These criteria are derived, in part, from the inclusion criteria of the comparative clinical trials and include a requirement that there be a beneficiary specific reason for choosing PUL instead of TURP or other tissue destructive approach. Beneficiary specific reasons for choosing PUL include comorbid medical illness which increases the risk associated with TURP, risk of bleeding rendering a less invasive approach preferred, or a beneficiary's desire to maintain erectile function (since the clinical trials have shown an advantage in this regard).

**Indications:**

Prostatic urethral lift procedures are reasonable and necessary when ALL of the following criteria are met:

- The UroLift device is used for the treatment of symptomatic BPH in a beneficiary at least 50 years old with well documented voiding symptoms consistent with prostatic hypertrophy; and
- AUA symptom index (AUASI) score greater than or equal to 13; and
- Peak urine flow rate (Qmax) less than or equal to 12 cc/sec on a voided volume that is greater than 125 cc); and
- The beneficiary has had an adequate trial of, but is refractory to or intolerant of, usual BPH medication; and
- The prostate volume is less than or equal to 80 cc without an obstructive median lobe; and
- There are no signs, symptoms, or diagnostic evidence of an active urinary infection and no history of bacterial prostatitis in the past 1 year; and
- Renal function is normal; and
- The beneficiary is a poor candidate for other surgical interventions for BPH due to underlying disease (e.g. cardiac disease, pulmonary disease, etc.) and/or at high risk of bleeding and/or the beneficiary has opted for PUL based on likelihood of preserving erectile function and/or there is another documented clinical reason for opting for PUL.

Prostatic Urethral Lift (PUL) AB

Limitations:

Coverage is for surgical intervention with up to a total of six implants. Implants in excess of six will deny. However, exceptions will be allowed on a case by case basis during the appeals process when the documentation supports the medical necessity of additional implants (more than 6), for a particular patient. The contractor expects that this should be infrequent and performed only on an exceptional basis.

Type of Bill Code

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

012x Hospital Inpatient (Medicare Part B only)
013x Hospital Outpatient
083x Ambulatory Surgery Center
085x Critical Access Hospital

Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

036X
096X

CPT/HCPCS Codes

Group 1 Paragraph: CPT codes 52441 and 52442 should be billed to the Part B MAC. HCPCS codes C9739 and C9740 should be billed to the Part A MAC. HCPCS codes C9739 and C9740 can also be billed by Ambulatory Surgical Centers (ASCs) to the Part B MAC.

Group 1 Codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>52441</td>
<td>CYSTOUHERETHROSCOPY, WITH INSERTION OF PERMANENT ADJUSTABLE TRANSPROSTATIC IMPLANT; SINGLE IMPLANT</td>
</tr>
<tr>
<td>52442</td>
<td>CYSTOUHERETHROSCOPY, WITH INSERTION OF PERMANENT ADJUSTABLE TRANSPROSTATIC IMPLANT; EACH ADDITIONAL PERMANENT ADJUSTABLE TRANSPROSTATIC IMPLANT (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)</td>
</tr>
<tr>
<td>C9739</td>
<td>CYSTOUHERETHROSCOPY, WITH INSERTION OF TRANSPROSTATIC IMPLANT; 1 TO 3 IMPLANTS</td>
</tr>
<tr>
<td>C9740</td>
<td>CYSTOUHERETHROSCOPY, WITH INSERTION OF TRANSPROSTATIC IMPLANT; 4 OR MORE IMPLANTS</td>
</tr>
</tbody>
</table>

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: The correct use of an ICD-10-CM code listed below does not assure coverage of a service. The service must be reasonable and necessary in the specific case and must meet the criteria specified in this determination.

Group 1 Codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N40.1</td>
<td>Enlarged prostate with lower urinary tract symptoms</td>
</tr>
</tbody>
</table>

ICD-10 Codes that DO NOT Support Medical Necessity
Associated Information

Documentation Requirements

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (See "Indications and Limitations of Coverage.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

The medical record should clearly document:

- Trial(s) of medical therapy attempted and reason for discontinuation or reason patient is not a suitable candidate for the usual BPH medication(s);
- Prostatic volume as measured by ultrasound;
- Absence of obstructive median lobe;
- BPH symptoms and AUASI score;
- Rationale for choosing PUL (e.g. simple chart notation indicating patient preferred PUL over TURP because of concerns about erectile function).

Utilization Guidelines

The Prostatic Urethral Lift procedure can only be performed once in a lifetime per beneficiary. Coverage is available for up to a total of six implants per Prostatic Urethral Lift procedure.

Sources of Information and Basis for Decision

This bibliography presents those sources that were obtained during the development of this policy. First Coast is not responsible for the continuing viability of Web site addresses listed below.


Prostatic Urethral Lift (PUL) AB


Start Date of Comment Period

06/02/2016

End Date of Comment Period

07/16/2016

Start Date of Notice Period

09/15/2016

Revision History

Revision Number: Original
Publication: September Connection
LCR 2016

Related Documents

N/A

LCD Attachments

N/A